K061055

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# 510(k) Premarket Notification
# for
# Life-Shield Products, Inc.
# CAREO Safety Syringe for U-100 Insulin
*(per 21 CFR807.92)*

JUL 10 2006

## 1. Sponsor


Life-Shield Products, Inc.
3Fl., No. 10, Wuchiuan 7th Rd.,
Wugu Industrial Park,
Taipei 248
Taiwan, R.O.C.
Contact Person: Mr. Hsiao, Chung-Chih
Telephone: +886 2 2299 6033
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Date Prepared: April 15, 2006

## 2. Device Name

| | |
|---|---|
| Proprietary Name: | CAREO Safety Syringe for U-100 Insulin |
| Common/Usual Name: | Syringe |
| Classification Code: | MEG |
| Classification Name: | Syringe, Antistick |

## 3. Predicate Device

- 1cc Insulin SafePro* Safety Syringe (K050134)
- CAREO Safety Syringe 1cc/mL (K060208)

## 4. Device Description

The Life-Shield Products, Inc., CAREO Safety Syringe for U-100 Insulin is a sterile, single use and disposable, 1cc/mL piston syringe, provided with a permanently attached needle in nine product configurations. The CAREO Safety Syringe for U-100 Insulin is similar in appearance, size, materials operation, and purpose to the cited predicate device and other conventional single use, sterile, disposable syringes.

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## 5. Intended Use

The CAREO Safety Syringe for U-100 Insulin is a sterile, single-use, disposable and non-reusable, retractable safety syringe which is intended to provide a safe and reliable method for injection of insulin into a patient.

The CAREO Safety Syringe for U-100 Insulin is also intended to prevent needlestick injuries. In addition, when the user breaks the plunger, reuse of the syringe is prevented.

## 6. Technological Characteristics and Substantial Equivalence

Life-Shield Products, Inc., makes a claim of substantial equivalence of the CAREO Safety Syringe for U-100 Insulin to the 1cc Insulin SafePro* Safety Syringe (K050134) and CAREO Safety Syringe 1cc/mL (K060208) based on similarities in intended use, design, technological and operational characteristics. All are indicated for injecting fluids (insulin) into the body, while helping to reduce the risk of sharps injuries. All syringes are piston syringes that use permanently attached single lumen hypodermic needles. All syringes are provided sterile, single-use, and disposable. All syringes require the user to manually retract the needle-plunger into the syringe barrel, snap off the plunger rod, and discard the pieces.

## 7. Summary for testing of material and simulated use study

The materials of construction, safety feature, and other functional and performance characteristics of CAREO Safety Syringe for U-100 Insulin are identical to those for the other CAREO Safety Syringes. The material safety test, biocompatibility, and safety feature were already indicated, verified, and validated as shown in the previous 510(k) premarket notifications [K030976, K052397, and K060208]. Therefore, no new tests are necessary.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 10 2006

Mr. Chung-Chih Hsiao
Senior Regulatory Affairs Consultant
Life-Shield Products, Incorporated
3Fl, No. 10, Wuchiuan 7th Road
Wugu Industrial Park
Taipei 248
TAIWAN R.O.C.

Re: K061055
Trade/Device Name: Life-Shield Products, Inc., CAREO Safety Syringe for U-100 Insulin
Regulation Number: 880.5860
Regulation Name: Piston Syringe
Regulatory Class: II
Product Code: MEG
Dated: April 15, 2006
Received: April 17, 2006

Dear Mr. Hsiao:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K061055
1.61

510(k) Number (if known):

Device Name : Life-Shield Products, Inc., CAREO Safety Syringe for U-100 Insulin

Indications for Use:

The CAREO Safety Syringe for U-100 Insulin is a sterile, single-use, disposable and non-reusable, retractable safety syringe which is intended to provide a safe and reliable method for injection of insulin into a patient.

The CAREO Safety Syringe for U-100 Insulin is also intended to prevent needlestick injuries. In addition, when the user breaks the plunger, reuse of the syringe is prevented.

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|---|---|---|
| Prescription Use _____<br>(21 CFR 801 Subpart D) | OR | Over-The-Counter Use ___X___<br>(21 CFR 801 Subpart C) |

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NESSARY)

Concurrence of CDRH, Office of Device Evaluation (ODE)

[signature]
...ion Sign-Off)
...n of Anesthesiology, General Hospital,
...ion Control, Dental Devices
...Number: K061455